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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/415,540	10/08/1999	PHILLIP R. HAWKINS	PF-0148-3 CPA	4965

27904 7590 12/31/2002

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/415,540	HAWKINS ET AL.
	Examiner Elizabeth Slobodyansky	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) Other: _____

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DETAILED ACTION

The amendment filed October 9, 2002 canceling claims 21 and 22 and amending claim 20 has been entered.

Claims 18-20 are pending.

Claim Objections

Claim 20 is objected to because of the following informalities: "polynucleotide" on line 2, at the first occurrence is mistyped. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19, with dependent claims 18 and 20, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 recites "a naturally-occurring human polynucleotide sequence variant encoding an amino acid sequence having at least 90% sequence identity to the

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sequence of SEQ ID NO:1", thus encompassing all allelic variants of SEQ ID NO:1.

There is no limitation on the function of the encoded protein. Thus, the genus of polynucleotides of claim 19 encodes proteins having pyrophosphatase activity and many inactive variants thereof.

Allelic variants are alternate forms of a gene which have at least one mutation in the nucleotide sequence which may result in mRNAs (polypeptides) with altered function. With regard to a naturally-occurring human polynucleotide sequence variant, there is no description of any mutational site that exist in nature, and there is no description of how the structure of SEQ ID NO:2 relates to the structure of any allele including strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. Thus the claimed genus is extremely variable with the potential to encode proteins with widely variant functions. The common attributes of the genus are not described. Therefore, one of skill in the art would not conclude that applicant was in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claims.

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Therefore, a naturally-occurring human DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 having no pyrophosphatase function lacks sufficient written description needed to practice the invention of claims 18-20.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is confusing as reciting "60 contiguous nucleotides comprising a sequence completely complementary to SEQ ID NO:2" (emphasis added) because SEQ ID NO:2 has 1275 nucleotides. Amending the claim to recite "60 contiguous nucleotides of a sequence completely complementary to SEQ ID NO:2" would obviate this rejection.

Response to Arguments

Applicant's arguments filed October 9, 2002 have been fully considered but they are not persuasive.

With regard to the written description of a polynucleotide of claim 19 (SEQ ID NO: 2 or a naturally-occurring human polynucleotide encoding an amino acid sequence

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having at least 90% sequence identity to the sequence of SEQ ID NO:1) Applicants refer to "the reasons already made of record in Applicants' Brief on Appeal" (Remarks; page 3). Said arguments have been responded to in the Office action mailed June 4, 2002 (pages 10-11). Applicants further argue that "the written description standard is fulfilled by both what is specifically disclosed and what is conventional or well known to one skilled in the art (page 4). This is not persuasive because Applicants specifically disclose only a single representative of the entire claimed genus, SEQ ID NO:2. Said claimed genus is extremely variable with the potential to encode proteins with widely variant functions. The correlation between structure and function common to the members of the genus is not described. It is not conventional in the art to predict as to how the structure of one naturally-occurring sequence is representative of unknown sequences. Furthermore, no other naturally-occurring human polynucleotides encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 are known in the art.

Arguments with regard to the 112, 1st, enablement, 112, 2nd, 102(b) and 103(a) rejections are moot in view of the amendments. The examiner agrees that the Yang et al. sequence does not comprise 60 contiguous nucleotides of SEQ ID NO:2 (page 8).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

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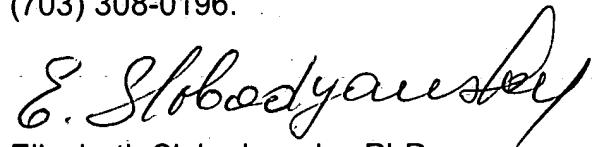
706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner

December 24, 2002